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Product No.	104
Lot No.	DR43-2



CTS Collaborative Transplant Study

WORKING INSTRUCTION

HLA-DRB1* CTS-PCR-SSP TRAY KIT

LOCUS- AND LOT-SPECIFIC MANUAL

To be applied to the following product:

Product No.	Description
104	HLA-DRB1* CTS-PCR-SSP TRAY KIT  

1. Main differences

- **Between lot DR43-2 (the current lot) and the previous lots (DR43-1):**
The kit was updated to cover new alleles included in the IMGT/HLA Sequence Database of April 2022. Deleted and renamed alleles were taken into consideration.

2. Introduction

- Intended use: This kit reveals a low/intermediate resolution typing of HLA-DRB1* (besides HLA-DRB3*/4*/5* low resolution) by the PCR-SSP method.
Allele coverage: IMGT/HLA Sequence Database Release 3.48.0, April 2022, except:
DRB1*01:01:31/01:02:12/01:18:01-01:18:02/01:22/01:33N/01:44:01-01:44:02/01:60/01:76/01:134,
DRB1*04:11:04/04:156, DRB1*08:01:06/08:04:02/08:57/08:80, DRB1*09:09/09:23, DRB1*10:12, DRB1*11:02:03/
11:04:13/11:86/11:94/11:110/11:123/11:156/11:167/11:172/11:185/11:187/11:192/11:208/11:294N,
DRB1*12:31N/12:42/12:57/12:83, DRB1*13:195, DRB1*14:231N, DRB1*15:01:22/15:34, DRB1*16:50,
DRB3*01:68/01:95, DRB3*02:26-02:27/02:47/02:58/02:66/02:91/02:111/02:131/02:143/02:160,
DRB4*01:01:01:04-01:01:10/01:03:03-01:157, DRB4*03:01N, DRB5*01:01:10/01:51/01:74/01:79Q/01:87/01:97/
01:110.
These alleles are considered to be rare.
- This manual is only valid for **Lot No. DR43-2**.
- This manual should be used together with the Main Manual (General Information) which is the 'Working instruction for the CTS-PCR-SSP **TRAY and MINITRAY KITS**' (Manual No. 100A).

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4. Kit Composition

- Number of PCR primer mixes per test: 24:
 - 23 HLA-specific mixes
 - 1 negative control mix
- Number of tests per tray: 4
- Number of trays per kit: 10
- The primer mixes are aliquoted and dried in PCR-Trays.
- PCR buffer: 3.0 ml of Mastermix SSP (without Taq polymerase).

For storage condition, please refer to Section 1 of the 'Working instruction for the CTS-PCR-SSP TRAY and MINITRAY KITS' (Manual No. 100A) supplied along with this product.

5. Materials, Reagents and Equipment not supplied

Please refer to Section 2 of the 'Working instruction for the CTS-PCR-SSP TRAY and MINITRAY KITS' (Manual No. 100A) supplied along with this product.

6. Sample Requirements, PCR and Gel Electrophoresis

Please refer to Section 3 to 6 of the 'Working instruction for the CTS-PCR-SSP TRAY and MINITRAY KITS' (Manual No. 100A) supplied along with this product.

7. Result Evaluation

- Check the approximate size of the PCR product against the Primer Mix Specificity Table (Appendix / Table 1) to confirm the correct product size.
- Use the Amplification Pattern Table (Appendix / Table 2) to make the allele assignments or use the SCORE Software for detailed result interpretation.

8. Interpretation Hints

- Weak or false positive reactions can occur if you use a different Taq polymerase. In addition, the quality and quantity of DNA is a crucial factor and can affect the mix reactivities. Under suboptimal test conditions, some mixes could give rise to false positive reactions (if there are any potentially false positive reactions when using this specific lot, they are indicated in Section 9).
- Alleles that are known to amplify weakly are listed with "w" (= weak) in the tables (Appendix).
- Please also refer to Section 7 and 8 of the 'Working instruction for the CTS-PCR-SSP TRAY and MINITRAY KITS' (Manual No. 100A) supplied along with this product.

9. Special notes

- Mix 5 and mix 6 detect (among other alleles) the most common HLA-DRB1*03 alleles which correspond either to serological split HLA-DR17 or HLA-DR18, respectively.
- The following mix could give a false positive reaction: Mix 7.

10. Troubleshooting

Please refer to Section 8 of the 'Working instruction for the CTS-PCR-SSP TRAY and MINITRAY KITS' (Manual No. 100A) supplied along with this product.

11. Precaution

Please refer to Material Safety Data Sheet for the CTS-PCR-SSP TRAY and MINITRAY KITS (Manual No. 100B) supplied along with this product.

12. Contact

If you have any particular questions concerning this kit, which are not answered in this or the Main Manual, please do not hesitate to contact us at:

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13. Appendix

Table 1: Allele specificities and sizes of the PCR products of each **HLA-DRB1*** CTS-PCR-SSP primer mix (**Lot No. DR43-2**) based on IMGT/HLA Sequence Database Release 3.48.0, April 2022

Position				Mix	Allele	Serology	Size
H1	H4	H7	H10	Mix 1	DRB1*01:01:01:01-01:01:01:30/01:01:32-01:02:11/01:02:13-01:17/01:19-01:21/01:23-01:32/01:34-01:38/01:39Nw-01:40Nw/01:41-01:43/01:45-01:48/01:49w/01:50-01:59/01:61-01:64/01:65:01w-01:65:02w/01:66-01:75/01:77-01:133/01:135	DR1, -, DR103, Null	140 bp
G1	G4	G7	G10	Mix 2	DRB1*15:01:01:01-15:01:21/15:01:23-15:33/15:35-15:112/15:113Nw/15:114-15:206, DRB1*16:09:01-16:10:02/16:33/16:36-16:37/16:58/16:66	DR15(2), -, DR2, Null, DR16(2)	140bp/ 215bp
F1	F4	F7	F10	Mix 3	DRB1*15:21, DRB1*16:01:01:01-16:01:08/16:01:09w/16:01:10-16:05:02/16:07-16:49/16:51-16:72	-, DR16(2), DR2, Null	210 bp
E1	E4	E7	E10	Mix 4	DRB1*03:01:01:01-03:01:01:06/03:01:02:01w-03:01:02:02w/03:01:03/03:01:05-03:01:13/03:01:14w/03:01:15-03:02:01:02/03:02:02w/03:02:03-03:05:02/03:05:03w/03:06-03:11:01/03:11:03-03:13:01/03:13:02w/03:14-03:15:01:01/03:15:01:02w-03:15:02w/03:16-03:41:02/03:43-03:75/03:77-03:83/03:85-03:86/03:88-03:91/03:93-03:96/03:98-03:110/03:112-03:124/03:127w/03:128-03:129/03:130w/03:131-03:134/03:135w/03:136-03:144/03:145w/03:146-03:156N/03:158-03:161/03:163-03:173/03:175-03:176/03:178-03:189N/03:190w/03:192-03:195, DRB1*11:07:01/11:07:02w/11:53/11:103:01-11:103:02/11:105/11:107/11:125/11:136/11:173, DRB1*14:104w/14:111w/14:171, DRB3*01:14w	DR17(3), -, DR18(3), DR3, Null, DR11(5)	225 bp
D1	D4	D7	D10	Mix 5	DRB1*03:01:01:01-03:01:41/03:04:01-03:04:02/03:06/03:08/03:10-03:11:01/03:11:03/03:12?/03:13:01-03:13:02/03:15:01:01-03:16/03:18-03:20/03:22-03:23/03:25:01-03:26/03:28/03:30-03:34/03:36-03:37/03:39/03:42-03:48/03:50-03:52:02/03:54w/03:55-03:56/03:58-03:62/03:64-03:73/03:75-03:80/03:82-03:87/03:89/03:91-03:96/03:98-03:99/03:100:01w-03:100:02w/03:104/03:106-03:112/03:114/03:116-03:118/03:121/03:123-03:129/03:132-03:153/03:156N-03:166/03:168-03:170/03:172-03:175/03:177/03:180-03:184/03:186-03:187/03:189N-03:195, DRB1*09:06, DRB1*11:59/11:83/11:135/11:182, DRB1*13:27:01-13:27:02/13:71/13:129/13:144/13:176/13:326, DRB1*14:82/14:95/14:132, DRB3*01:34, DRB3*03:33	DR17(3), -, DR3, Null, DR13(6)	220 bp
C1	C4	C7	C10	Mix 6	DRB1*03:02:01:01-03:02:05/03:05:01-03:05:03/03:09/03:14/03:27/03:29/03:38/03:53/03:74/03:81/03:88/03:90/03:102-03:103/03:115/03:122/03:130-03:131/03:154/03:167/03:176/03:178-03:179/03:188, DRB1*11:09:01:01-11:09:01:02/11:20/11:28:02/11:87/11:122, DRB1*13:02:01:01-13:02:03/13:02:05-13:02:20/13:05:01:01-13:05:03/13:26:01-13:26:02/13:29:01:01-13:29:01:02/13:31/13:34/13:36/13:39/13:41/13:50:02-13:50:03/13:56/13:63/13:65/13:67/13:73-13:74/13:85/13:96:01-13:96:02/13:99/13:103-13:104/13:109/13:119-13:120/13:123-13:124/13:126/13:128/13:136/13:139-13:140/13:142N-13:143/13:145/13:147/13:155/13:157-13:159/13:165/13:168/13:170-13:171:02/13:179/13:189/13:196/13:198-13:199/13:202-13:203/13:207-13:212/13:220/13:225/13:235-13:237/13:239-13:241/13:243-13:244/13:255N/13:257/13:264-13:265/13:268N-13:269/13:275/13:277/13:280/13:282/13:285/13:288-13:289N/13:292-13:293/13:296-13:298N/13:301-13:302/13:306/13:310N/13:312/13:318/13:320/13:325, DRB1*14:02:01:01-14:02:07/14:02:09-14:03:02/14:09/14:13/14:19/14:24/14:27:01-14:27:02/14:30/14:46-14:48/14:51/14:63/14:67/14:85/14:89/14:98/14:109/14:115/14:134-14:135/14:144/14:174/14:179/14:194/14:198/14:200/14:209/14:218/14:222N-14:223/14:226/14:239/14:242, DRB1*16:08, DRB3*01:08/01:46/01:52/01:71, DRB3*02:06?/02:20	DR18(3), -, DR3, DR17(3), DR11(5), DR13(6), Null, DR14(6), DR1403	190 bp

Position				Mix	Allele	Serology	Size
B1	B4	B7	B10	Mix 7	DRB1*03:49, DRB1*04:01:01:01-04:05:11/04:05:13-04:11:03/04:11:05-04:155/04:157N-04:342, DRB1*08:38, DRB1*11:22/11:102:01-11:102:02/11:175/11:275/11:278, DRB1*14:10:01:01-14:10:01:02/14:57/14:143/14:161/14:182	-, DR4, Null, DR14(6)	85 bp/ 145 bp/ 200 bp/ 260 bp
A1	A4	A7	A10	Mix 8	DRB1*01:21w, DRB1*07:01:01:01-07:01:29/07:03-07:136	-, DR7, Null	115 bp/ 190 bp
H2	H5	H8	H11	Mix 9	DRB1*08:01:01-08:01:02/08:01:04-08:01:05/08:01:07-08:04:01:02/08:04:03-08:19/08:21-08:30:03/08:32-08:56/08:58-08:66/08:68:01-08:79/08:81-08:113, DRB1*11:67/11:193:01-11:193:02, DRB1*12:16:01-12:16:03/12:22/12:39:01-12:39:02/12:46/12:96, DRB1*14:04:01:01-14:04:09/14:15/14:28/14:31/14:50:01-14:50:02/14:68:01-14:68:02/14:71/14:73/14:76/14:79/14:93/14:107/14:120/14:138/14:145/14:148/14:152N/14:180/14:196/14:201/14:205:01/14:205:02?/14:206/14:210Q/14:220/14:224/14:229/14:233/14:241	DR8, -, Null, DR1404, DR14(6)	165 bp/ 215 bp/ 250 bp
G2	G5	G8	G11	Mix 10	DRB1*09:01:02:01-09:05/09:07-09:08/09:10-09:22/09:24-09:51	DR9, -, Null	220 bp
F2	F5	F8	F11	Mix 11	DRB1*01:34w, DRB1*10:01:01:01/10:01:01:03-10:11/10:13-10:30/10:31w/10:32-10:44:01:02	-, DR10	205 bp
E2	E5	E8	E11	Mix 12	DRB1*01:75, DRB1*03:08/03:65/03:140, DRB1*04:15/04:61/04:138/04:145/04:154/04:170/04:265/04:291/04:323/04:339, DRB1*08:31/08:41/08:63/08:75, DRB1*10:23, DRB1*11:01:01:01/11:01:01:03-11:02:02/11:02:04-11:04:12/11:04:14-11:11:01/11:11:03-11:21/11:22?/11:23:01-11:25/11:26?/11:27:01-11:39/11:40?/11:41-11:70/11:72-11:85/11:87-11:93/11:95-11:109/11:111-11:122/11:124:01-11:155/11:157-11:166/11:168-11:171/11:173-11:184/11:186/11:188-11:191/11:193:01-11:202/11:203w/11:204-11:207/11:209-11:210/11:211w/11:212-11:253/11:254w/11:255-11:263/11:265-11:292/11:295-11:302, DRB1*12:04/12:49, DRB1*14:11:01:01-14:11:01:02, DRB1*15:99/15:109, DRB1*16:16/16:27, DRB3*01:42, DRB3*02:18, DRB5*01:13/01:41	-, DR4, DR11(5), DR11(5)/DR13(6), Null, DR14(6)	125 bp
D2	D5	D8	D11	Mix 13	DRB1*08:25/08:32/08:47/08:53/08:87, DRB1*12:01:01:01-12:01:04/12:01:05w/12:01:06-12:19:02/12:20w/12:21-12:30/12:32-12:41/12:43-12:56/12:58-12:82/12:84-12:88/12:89?/12:90-12:97	-, DR12(5), Null	105 bp/ 210 bp
C2	C5	C8	C11	Mix 14	DRB1*03:125, DRB1*11:09:01:01-11:09:01:02/11:16:01:01-11:16:01:02/11:20/11:28:02/11:40w/11:58:01/11:59w/11:83/11:87/11:113/11:115/11:122w/11:182, DRB1*13:01:01:01-13:02:20/13:05:01:01-13:06/13:10/13:15-13:16:01:02/13:18/13:26:01-13:28:02/13:31-13:32/13:34-13:36/13:39-13:42:02/13:50:02-13:51/13:53/13:59/13:61:01-13:61:02/13:63w/13:65/13:67/13:69/13:73-13:74/13:79-13:80/13:85/13:87/13:91-13:93/13:96:01-13:96:02/13:98-13:99/13:102-13:105/13:109-13:110/13:111w/13:112-13:113N/13:117:01:01-13:117:01:02/13:120-13:121/13:123-13:128/13:130-13:131/13:136-13:148/13:153/13:155-13:160/13:165-13:166/13:168/13:170-13:171:02/13:173/13:176-13:177/13:179/13:183-13:187/13:189-13:191/13:198-13:203/13:205/13:207-13:215/13:217-13:218/13:220-13:222/13:223w/13:225-13:226/13:233/13:234w/13:236-13:245/13:248-13:249N/13:251-13:252N/13:254-13:275/13:277/13:279-13:283/13:285/13:287-13:294/13:296w/13:297-13:306/13:308-13:311/13:313/13:315/13:318/13:320/13:322N-13:325/13:327, DRB1*14:27:01-14:27:02/14:63/14:67/14:78, DRB1*16:08	-, DR11(5), DR11(5)/DR13(6), DR13(6), Null, DR14(6)	130 bp

Position				Mix	Allele	Serology	Size
B2	B5	B8	B11	Mix 15	DRB1*03:12/03:155/03:158, DRB1*11:03:01-11:03:04/11:11:01/11:11:03/11:36/11:40-11:41/11:55/11:59/11:63:01-11:63:02/11:68/11:76/11:85/11:122/11:138-11:139/11:151/11:161/11:168/11:176/11:213/11:231/11:233/11:237/11:241/11:260/11:301N, DRB1*13:03:01:01-13:04/13:12:01-13:13/13:20:01:01-13:21:02/13:24:01:01-13:24:01:03/13:29:01:01-13:30/13:32-13:33:03/13:38/13:43/13:48-13:49:02/13:54-13:55/13:58/13:63/13:65-13:66:02/13:71/13:75/13:78/13:81/13:88-13:90/13:93-13:95/13:101/13:108/13:111/13:115/13:118/13:120/13:122/13:133-13:134/13:139/13:149/13:151-13:152/13:154/13:161/13:164/13:167/13:169/13:174/13:188/13:194/13:216/13:219/13:227-13:228/13:230/13:247/13:253/13:276/13:295N/13:307/13:317/13:319N/13:321, DRB1*14:13/14:63/14:65/14:78/14:85/14:169-14:170	DR3, -, DR11(5), Null, DR13(6), DR14(6)	170 bp/ 200 bp
A2	A5	A8	A11	Mix 16	DRB1*11:09:01:01-11:09:01:02/11:28:02/11:40w/11:58:01/11:59w/11:83/11:87/11:113/11:115/11:122w/11:182, DRB1*13:05:01:01-13:05:03/13:18/13:26:01-13:26:02/13:42:01-13:42:02/13:50:02-13:50:03/13:63w/13:111w/13:136/13:144/13:158:01-13:158:02/13:189/13:199/13:203/13:277/13:302, DRB1*14:27:01-14:27:02, DRB1*16:08	DR11(5), -, DR13(6), DR14(6)	130 bp
H3	H6	H9	H12	Mix 17	DRB1*03:01:01:01-03:01:06/03:01:07w/03:01:08-03:01:13/03:01:14w/03:01:15-03:07:02/03:09-03:11:01/03:11:03-03:37/03:38w/03:39-03:41:02/03:43-03:45/03:46w/03:47-03:58/03:59w/03:60-03:64/03:66-03:78/03:79w/03:80-03:86/03:88-03:110/03:112-03:126/03:127w/03:128-03:129/03:130w/03:131-03:134/03:135w/03:136-03:139/03:141-03:155/03:157-03:161/03:163-03:186/03:187?/03:188-03:189N/03:190w/03:191-03:195, DRB1*08:01:01-08:01:02/08:01:04-08:01:05/08:01:07-08:04:01:02/08:04:03-08:24:02/08:25w/08:26-08:30:03/08:32-08:33/08:34w/08:35-08:40/08:42-08:46/08:47w/08:48-08:51/08:52w/08:53-08:56/08:58-08:62/08:64-08:68:02/08:70-08:74/08:76-08:79/08:81-08:108/08:109w/08:110-08:111/08:112w-08:113w, DRB1*11:264/11:293, DRB1*12:01:01:01w-12:01:07w/12:01:09w-12:02:05w/12:02:07w-12:03:03w/12:05w-12:08w/12:09/12:10w-12:17w/12:19:01w-12:23w/12:24N-12:25/12:26w-12:30w/12:32w/12:34w-12:41w/12:43w-12:45w/12:46/12:48/12:50w-12:53w/12:54/12:55w-12:56w/12:58w-12:61w/12:62/12:63w-12:66w/12:67/12:68w-12:75w/12:76/12:77w-12:82w/12:84w-12:88w/12:89?/12:90w-12:95w/12:96/12:97w, DRB1*13:01:01:01-13:02:11/13:02:12w/13:02:13-13:53/13:54w/13:55-13:66:02/13:68-13:76/13:77w/13:78-13:99/13:100w/13:101-13:102/13:103w/13:104-13:159/13:160w/13:161/13:162w/13:163-13:164/13:165w/13:166-13:182/13:184-13:194/13:196-13:198/13:199w/13:201-13:217/13:218w/13:219-13:227/13:229-13:247/13:250-13:298N/13:300-13:327, DRB1*14:01:01-14:09/14:12:01-14:38:02/14:40-14:45/14:47/14:48w/14:49-14:54:01:13/14:54:03-14:54:07/14:54:08w/14:54:09-14:56/14:58-14:60/14:62-14:65/14:67-14:124/14:125w/14:126:01-14:140/14:142/14:144-14:147/14:149-14:176/14:177w/14:178-14:181/14:183-14:194/14:195Nw/14:196-14:198/14:200-14:221/14:223-14:230/14:232-14:243, DRB3*01:14w	DR17(3), -, DR18(3), DR3, Null, DR8, DR12(5), DR13(6), DR14(6), DR1403, DR1404, DR6	165 bp/ 170 bp/ 175 bp
G3	G6	G9	G12	Mix 18	DRB1*03:10/03:97/03:126/03:191, DRB1*08:08/08:29, DRB1*11:17/11:52-11:54:02/11:89/11:150/11:159/11:202/11:267/11:283/11:293, DRB1*12:66/12:96, DRB1*13:43/13:45/13:76/13:159/13:171:01/13:179/13:188/13:191/13:197/13:206/13:217/13:302, DRB1*14:01:01-14:01:05/14:04:01:01-14:05:05/14:07:01-14:08/14:11:01:01-14:11:01:02/14:14/14:16/14:18/14:22-14:23:04/14:25:01-14:26/14:28/14:31-14:33/14:35-14:36/14:38:01-14:39/14:42-14:45/14:49-14:51/14:53-14:56/14:58-14:62/14:64/14:68:01-14:76/14:79/14:82/14:86-14:88/14:90-14:93/14:95-14:97/14:99/14:101/14:103-14:107/14:110-14:114/14:117-14:120/14:122/14:124/14:125w/14:126:01-14:126:02/14:128-14:134/14:137N-14:140/14:142/14:145-14:155/14:157-14:158/14:160-14:164/14:166N-14:169/14:171-14:173/14:175/14:178/14:180/14:184-14:193/14:196-14:197N/14:199-14:208/14:210Q-14:211/14:213-14:217/14:219-14:221/14:224-14:225/14:227-14:230/14:232-14:238/14:240-14:241/14:243	DR17(3), -, DR11(5), DR14(6), DR1404, DR6, DR13(6), Null	175 bp/ 225 bp

Position				Mix	Allele	Serology	Size
F3	F6	F9	F12	Mix 19	DRB1*03:126/03:157w/03:177, DRB1*04:211, DRB1*11:09:01:01-11:09:01:02/11:28:02w/11:58:01w/11:83/11:87/11:113/11:115w/11:182/11:280, DRB1*12:58, DRB1*13:05:01:01-13:06/13:18/13:26:01-13:26:02/13:42:01-13:42:02/13:50:02w-13:50:03w/13:56/13:77/13:119/13:136/13:144/13:146/13:156-13:158:02/13:163/13:181/13:189w/13:193/13:199/13:203/13:235/13:277/13:302, DRB1*14:02:01:01-14:03:02/14:06:01-14:06:06/14:09/14:12:01-14:13/14:17-14:18/14:27:01-14:27:02/14:29-14:30/14:33/14:46-14:48/14:51-14:52/14:59/14:63-14:64/14:67/14:78/14:80-14:81/14:83/14:85/14:89/14:95/14:98w/14:106/14:108/14:115/14:121/14:132-14:135/14:144/14:154/14:165/14:170/14:174/14:176-14:177/14:179/14:194-14:195N/14:198/14:200/14:209/14:212/14:218/14:222N-14:223/14:239/14:242, DRB1*16:08w	-, DR11(5), DR13(6), DR14(6), DR1403, DR6, Null	145 bp/ 150 bp
E3	E6	E9	E12	Mix 20	DRB1*09:07, DRB5*01:01:01:01-01:01:09/01:01:11-01:02:01/01:02:02w/01:03-01:25/01:26w/01:27N-01:47/01:48Nw/01:49N-01:50/01:52N-01:72/01:74w/01:75-01:78/01:80-01:86/01:88-01:96/01:98-01:109/01:111-01:112/01:113w/01:114-01:119, DRB5*02:02:01-02:31	-, DR51, Null	175 bp/ 210 bp
D3	D6	D9	D12	Mix 21	DRB1*03:42/03:87, DRB1*14:141, DRB3*01:01:02:01-01:13/01:15-01:67/01:69-01:94/01:96-01:100, DRB3*02:01-02:25/02:28-02:46/02:48-02:57/02:59-02:65/02:67N-02:77/02:78w/02:79-02:90/02:92-02:108/02:109Nw/02:110/02:112-02:116/02:117w/02:118-02:123/02:124w/02:125N-02:130/02:132-02:142/02:144-02:159/02:161/02:162w/02:163-02:178, DRB3*03:01:01:01-03:01:12/03:01:13w/03:01:14-03:21/03:23-03:45/03:46w/03:47-03:55	-, DR52, Null	215bp
C3	C6	C9	C12	Mix 22†	DRB4*01:01:01:01/01:01:01:03/01:02-01:03:01:01/01:03:01:03-01:03:01:12/01:03:01:14-01:03:02:02, DRB4*02:01N	DR53, -, Null	150 bp
B3	B6	B9	B12	Mix 23	DRB4*01:03:01:02N/01:03:01:13N	Null	165 bp
A3	A6	A9	A12	Mix 24	Negativ Control		None (440bp)

Amplification control (internal positive control): 440 base pairs (bp)

w = weak

? = nucleotide sequence information not available for the primer matching sequence or alleles with unknown reactivities

Mix 6: HLA-DRB1*03:81 serology unclear

HLA-DRB1*08:04:02 is not listed since the primer matching sequences are unknown.

† = Alleles which are not sequenced in the primer binding sites of mixes 22 (according to the IMGT/HLA Database of January 2022) have been excluded from the list of allele specificities of this mix: HLA-DRB4*01:01:02-01:01:09/01:03:03-01:13/01:15-01:61N/01:63-01:87/01:89-01:157.

Table 2: Amplification patterns of **HLA-DRB1*** and other HLA-DRB* alleles detected by the HLA-DRB1* CTS-PCR-SSP primer mixes (**Lot No. DR43-2**) based on IMGT/HLA Sequence Database Release 3.48.0, April 2022

Alleles	Serology	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23
DRB1*01:01:01:01-01:01:01:30/01:01:01:32-01:02:01:11/01:02:01:13-01:17:01:19-01:20:02:01:23-01:32:01:35-01:38/01:41-01:43/01:45-01:48/01:50-01:59/01:61-01:64/01:66-01:74/01:77-01:133/01:135	DR1, -, DR103, Null	1																						
DRB1*01:21	-	1							w															
DRB1*01:34	-	1										w												
DRB1*01:39N-01:40N/01:49/01:65:01-01:65:02	Null, -	w																						
DRB1*01:75	-	1											12											
DRB1*03:01:01:01-03:01:01:06/03:01:03/03:01:05-03:01:06/03:01:08-03:01:13/03:01:15-03:01:41/03:04:01-03:04:02/03:06/03:11:01/03:11:03/03:13:01/03:15:01:01/03:16/03:18-03:20/03:22-03:23/03:25:01-03:26/03:28/03:30-03:34/03:36-03:37/03:39/03:43-03:45/03:47-03:48/03:50-03:52:02/03:55-03:56/03:58/03:60-03:62/03:64/03:66-03:73/03:75/03:77-03:78/03:80/03:82-03:83/03:85-03:86/03:89/03:91/03:93-03:96/03:98-03:99/03:104/03:106-03:110/03:112/03:114/03:116-03:118/03:121/03:123-03:124/03:128-03:129/03:132-03:134/03:136-03:139/03:141-03:144/03:146-03:153/03:159-03:161/03:163-03:166/03:168-03:170/03:172-03:173/03:175/03:180-03:184/03:186/03:189N/03:192-03:195	DR17(3), -, DR3, Null				4	5												17						
DRB1*03:01:02:01-03:01:02:02/03:13:02/03:15:01:02-03:15:02/03:145	DR17(3), -				w	5												17						
DRB1*03:01:04/03:76/03:84/03:92/03:174N, DRB1*13:129/13:326	DR17(3), -, Null					5												17						
DRB1*03:01:07/03:46/03:59/03:79	DR17(3), -				4	5												w						
DRB1*03:01:14/03:127/03:135/03:190	-				w	5												w						
DRB1*03:02:01:01-03:02:01:02/03:02:03-03:02:05/03:05:01-03:05:02/03:09/03:14/03:27/03:29/03:53/03:74/03:81/03:88/03:90/03:102-03:103/03:115/03:122/03:131/03:154/03:167/03:176/03:178-03:179/03:188	DR18(3), -, DR3, DR17(3)				4	6												17						
DRB1*03:02:02/03:05:03	DR18(3), DR3				w	6												17						
DRB1*03:03/03:07:01:01-03:07:02/03:17/03:21/03:24/03:35/03:40-03:41:02/03:57/03:63/03:101/03:105/03:113/03:119-03:120/03:171/03:185	DR18(3), DR3, -				4													17						
DRB1*03:08/03:65/03:140	-				4	5							12											
DRB1*03:10	DR17(3)				4	5												17	18					
DRB1*03:12	DR3				4	?										15		17						
DRB1*03:38	-				4	6												w						
DRB1*03:42/03:87, DRB3*01:34, DRB3*03:33	-					5																21		

Alleles	Serology	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23
DRB1*03:49	-				4			7										17						
DRB1*03:54/03:100:01-03:100:02	-				4	w												17						
DRB1*03:97, DRB1*11:293, DRB1*13:45/13:76/13:197/13:206, DRB1*14:01:01-14:01:05/14:05:01:01-14:05:05/14:07:01-14:08/14:14/14:16/ 14:22-14:23:04/14:25:01-14:26/14:32:01-14:32:03/14:35-14:36/14:38:01- 14:38:02/14:42-14:45/14:49/14:53-14:54:01:13/14:54:03-14:54:07/14:54:09- 14:56/14:58/14:60/14:62/14:69-14:70/14:72/14:74-14:75/14:86-14:88/14:90- 14:92N/14:96-14:97/14:99/14:101/14:103/14:105/14:110/14:112-14:114/ 14:117-14:119/14:122/14:124/14:126:01-14:126:02/14:128-14:131/14:137N/ 14:139-14:140/14:142/14:146-14:147/14:149-14:151/14:153/14:155/14:157- 14:158/14:160/14:162-14:164/14:166N-14:168/14:172-14:173/14:175/14:178/ 14:184-14:193/14:197N/14:202-14:204/14:207-14:208/14:211/14:213-14:217/ 14:219/14:221/14:225/14:227-14:228/14:230/14:232/14:234-14:238/14:240/ 14:243	-, DR14(6), DR6, DR13(6), Null																	17	18					
DRB1*03:111/03:162, DRB1*09:06	-					5																		
DRB1*03:125, DRB1*13:27:01-13:27:02/13:176	-, DR13(6)					5									14			17						
DRB1*03:126, DRB1*14:95/14:132	-					5												17	18	19				
DRB1*03:130	-				w		6											w						
DRB1*03:155	-				4											15		17						
DRB1*03:156N	Null				4	5																		
DRB1*03:157	-					5												17		w				
DRB1*03:158	-				4	5										15		17						
DRB1*03:177	-					5												17		19				
DRB1*03:187	-				4	5												?						
DRB1*03:191, DRB1*14:82	-					5												17	18					
DRB1*04:01:01:01-04:05:11/04:05:13-04:11:03/04:11:05-04:14/04:16-04:60/ 04:62-04:137/04:139-04:144/04:146-04:153/04:155/04:157N-04:169/04:171- 04:210/04:212N-04:264N/04:266N-04:290/04:292-04:322/04:324-04:338/ 04:340-04:342, DRB1*14:10:01:01-14:10:01:02/14:57/14:143/14:182	DR4, -, Null, DR14(6)							7																
DRB1*04:15/04:61/04:138/04:145/04:154/04:170/04:265/04:291/04:323/ 04:339, DRB1*11:102:01-11:102:02/11:175/11:275/11:278	DR4, -							7					12											
DRB1*04:211	-							7													19			
DRB1*07:01:01:01-07:01:01:02-07:01:29/07:03-07:136	DR7, -, Null								8															

Alleles	Serology	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23
DRB1*08:01:01-08:01:02/08:01:04-08:01:05/08:01:07-08:04:01:02/08:04:03-08:07/08:09:01-08:19/08:21-08:24:02/08:26-08:28/08:30:01-08:30:03/08:33/08:35-08:37/08:39-08:40/08:42-08:46/08:48-08:51/08:54-08:56/08:58-08:62/08:64-08:66/08:68:01-08:68:02/08:70-08:74/08:76-08:79/08:81-08:86/08:88-08:108/08:110-08:111, DRB1*14:15	DR8, -, Null									9								17						
DRB1*08:08/08:29, DRB1*14:04:01:01-14:04:09/14:28/14:31/14:50:01-14:50:02/14:68:01-14:68:02/14:71/14:73/14:76/14:79/14:93/14:107/14:120/14:138/14:145/14:152N/14:180/14:196/14:201/14:205:01/14:206/14:210Q/14:220/14:224/14:229/14:233/14:241	-, DR1404, DR14(6), Null									9								17	18					
DRB1*08:20/08:67, DRB1*11:264, DRB1*13:07:01-13:09/13:11:01-13:11:02/13:14:01-13:14:03/13:17/13:19/13:22:01:01-13:23:02/13:25/13:37/13:44/13:46-13:47/13:50:01/13:52/13:57/13:60/13:62/13:64/13:68/13:70/13:72/13:82-13:84/13:86/13:97:01-13:97:02/13:106-13:107/13:114/13:116/13:132/13:135/13:150/13:172/13:175/13:178/13:180/13:182/13:192/13:204/13:224/13:229/13:231-13:232/13:246/13:250/13:278Q/13:284/13:286/13:314/13:316, DRB1*14:20-14:21/14:34/14:37/14:40-14:41/14:77/14:84/14:94/14:100/14:102/14:116/14:123/14:127:01-14:127:02/14:136/14:156/14:159/14:181/14:183	-, DR13(6), DR14(6)																	17						
DRB1*08:25/08:47, DRB1*12:16:01-12:16:03/12:22/12:39:01-12:39:02	-									9				13				w						
DRB1*08:31, DRB1*11:01:01:01/11:01:01:03-11:02:02/11:02:04-11:02:07/11:04:01:01-11:04:12/11:04:14-11:06:03/11:08:01-11:08:03/11:10:01-11:10:02/11:12:01-11:15:02/11:18-11:19:03/11:21/11:23:01-11:25/11:27:01-11:28:01:02/11:28:03-11:35/11:37:01-11:39/11:42:01-11:51/11:56-11:57/11:58:02/11:60-11:62:02/11:64-11:66:02/11:69-11:70/11:72-11:75/11:77-11:82/11:84:01-11:84:03/11:88/11:90-11:93/11:95-11:101:02/11:104/11:106/11:108-11:109/11:111-11:112/11:114/11:116-11:121/11:124:01-11:124:02/11:126-11:134/11:137/11:140-11:149/11:152-11:155/11:157-11:158/11:160/11:162-11:166/11:169N-11:171/11:174/11:177-11:181/11:183-11:184/11:186/11:188-11:191/11:194:01-11:201/11:204-11:207/11:209-11:210/11:212/11:214-11:230/11:232/11:234-11:236/11:238-11:240/11:242-11:253/11:255-11:259/11:261-11:263/11:265-11:266/11:268-11:274/11:276-11:277/11:279/11:281-11:282/11:284-11:292/11:295-11:300/11:302	DR11(5), -, Null												12											
DRB1*08:32/08:53/08:87, DRB1*12:46	-									9				13				17						
DRB1*08:34/08:52/08:109/08:112-08:113	-									9								w						
DRB1*08:38	-							7		9								17						
DRB1*08:41/08:63/08:75, DRB1*11:67/11:193:01-11:193:02	-									9			12											
DRB1*08:69	-									9														

Alleles	Serology	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23
DRB1*09:01:02:01-09:05/09:08/09:10-09:22/09:24-09:51	DR9, -, Null										10													
DRB1*09:07	-										10										20			
DRB1*10:01:01:01/10:01:01:03-10:11/10:13-10:22/10:24-10:30/10:32-10:44:01:02	DR10, -											11												
DRB1*10:23	-											11	12											
DRB1*10:31	-											w												
DRB1*11:03:01-11:03:04/11:11:01/11:11:03/11:36/11:41/11:55/11:63:01-11:63:02/11:68/11:76/11:85/11:138-11:139/11:151/11:161/11:168/11:176/11:213/11:231/11:233/11:237/11:241/11:260/11:301N	DR11(5), -, Null												12			15								
DRB1*11:07:01/11:103:01-11:103:02/11:105/11:107/11:125/11:136/11:173	DR11(5), -				4								12											
DRB1*11:07:02	-				w								12											
DRB1*11:09:01:01-11:09:01:02/11:87	DR11(5), -					6							12	14		16				19				
DRB1*11:16:01:01-11:16:01:02	DR11(5)/ DR13 (6), -												12	14										
DRB1*11:17/11:52/11:54:01-11:54:02/11:89/11:150/11:159/11:202/11:267/11:283, DRB1*14:11:01:01-14:11:01:02	-, DR11(5), DR14(6)												12						18					
DRB1*11:20	DR11(5)					6							12	14										
DRB1*11:22	-							7					?											
DRB1*11:26	DR11(5)												?											
DRB1*11:28:02	-					6							12	14		16				w				
DRB1*11:40	-												?	w	15	w								
DRB1*11:53	-				4								12						18					
DRB1*11:58:01/11:115	-												12	14		16				w				
DRB1*11:59	-					5							12	w	15	w								
DRB1*11:83/11:182	-					5							12	14		16				19				
DRB1*11:113	-												12	14		16				19				
DRB1*11:122	-						6						12	w	15	w								
DRB1*11:135	-					5							12											
DRB1*11:203/11:211/11:254	-												w											
DRB1*11:280	-												12							19				

Alleles	Serology	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23
DRB1*12:01:01:01-12:01:04/12:01:06-12:01:07/12:01:09-12:02:05/12:02:07-12:03:03/12:05-12:08/12:10-12:15/12:17/12:19:01-12:19:02/12:21/12:23/12:26-12:30/12:32/12:34-12:38/12:40-12:41/12:43-12:45/12:50-12:53/12:55-12:56/12:59-12:61/12:63-12:65/12:68-12:75/12:77-12:82/12:84-12:88/12:90-12:95/12:97	DR12(5), -, Null													13				w						
DRB1*12:01:05/12:20	-													w				w						
DRB1*12:01:08/12:02:06/12:18/12:33/12:47	-													13										
DRB1*12:04/12:49	-												12	13										
DRB1*12:09/12:24N-12:25/12:48/12:54/12:62/12:67/12:76	-, Null													13				17						
DRB1*12:58	-													13				w		19				
DRB1*12:66	-													13				w	18					
DRB1*12:89	-													?				?						
DRB1*12:96	-									9				13				17	18					
DRB1*13:01:01:01-13:01:39/13:02:04/13:10/13:15-13:16:01:02/13:28:01-13:28:02/13:35/13:40/13:51/13:53/13:59/13:61:01-13:61:02/13:69/13:79-13:80/13:87/13:91-13:92/13:98/13:102/13:105/13:110/13:112-13:113N/13:117:01:01-13:117:01:02/13:121/13:125/13:127/13:130-13:131/13:137N-13:138/13:141/13:148/13:153/13:166/13:173/13:177/13:184-13:187/13:190/13:201/13:205/13:213-13:215/13:221-13:222/13:226/13:233/13:238/13:242:01-13:242:02/13:245/13:251-13:252N/13:254/13:256/13:258-13:263/13:266-13:267/13:270-13:274/13:279/13:281/13:283/13:287/13:290-13:291/13:294/13:300/13:303-13:305/13:308-13:309/13:311/13:313/13:315/13:322N-13:324N/13:327	DR13(6), -, Null														14			17						
DRB1*13:02:01:01-13:02:03/13:02:05-13:02:11/13:02:13-13:02:20/13:31/13:34/13:36/13:39/13:41/13:73-13:74/13:85/13:96:01-13:96:02/13:99/13:104/13:109/13:123-13:124/13:126/13:128/13:140/13:142N-13:143/13:145/13:147/13:155/13:168/13:170/13:171:02/13:198/13:202/13:207-13:212/13:220/13:225/13:236-13:237/13:239-13:241/13:243-13:244/13:255N/13:257/13:264-13:265/13:268N-13:269/13:275/13:280/13:282/13:285/13:288-13:289N/13:292-13:293/13:297-13:298N/13:301/13:306/13:310N/13:318/13:320/13:325	DR13(6), -, Null						6								14			17						
DRB1*13:02:12/13:103/13:165	-						6								14			w						

Alleles	Serology	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23
DRB1*13:03:01:01-13:04/13:12:01-13:13/13:20:01:01-13:21:02/13:24:01:01-13:24:01:03/13:30/13:33:01-13:33:03/13:38/13:48-13:49:02/13:55/13:58/13:66:01-13:66:02/13:75/13:78/13:81/13:88-13:90/13:94:01-13:95/13:101/13:108/13:115/13:118/13:122/13:133-13:134/13:149/13:151-13:152/13:154/13:161/13:164/13:167/13:169/13:174/13:194/13:216/13:219/13:227/13:230/13:247/13:253/13:276/13:295N/13:307/13:317/13:319N/13:321, DRB1*14:65	DR13(6), -, Null															15		17						
DRB1*13:05:01:01-13:05:03/13:26:01-13:26:02/13:136/13:158:01-13:158:02/13:203/13:277, DRB1*14:27:01-14:27:02	DR13(6), -, DR14(6)						6								14		16	17		19				
DRB1*13:06/13:146/13:156	DR13(6), -														14			17		19				
DRB1*13:18/13:42:01-13:42:02	DR13(6), -														14		16	17		19				
DRB1*13:29:01:01-13:29:01:02	DR13(6), -						6									15		17						
DRB1*13:32/13:93	-														14	15		17						
DRB1*13:43/13:188, DRB1*14:169	-															15		17	18					
DRB1*13:50:02-13:50:03/13:189	-						6								14		16	17		w				
DRB1*13:54	DR14(6)															15		w						
DRB1*13:56/13:119/13:235, DRB1*14:02:01:01-14:02:07/14:02:09-14:03:02/14:09/14:30/14:47/14:89/14:115/14:135/14:144/14:174/14:179/14:194/14:198/14:209/14:218/14:223/14:239/14:242	-, DR14(6), DR1403						6											17		19				
DRB1*13:63	-						6								w	15	w	17						
DRB1*13:65/13:120/13:139	-						6								14	15		17						
DRB1*13:67	-						6								14									
DRB1*13:71	-						5									15		17						
DRB1*13:77, DRB1*14:177/14:195N	-, Null																	w		19				
DRB1*13:100/13:162	-																	w						
DRB1*13:111	-														w	15	w	17						
DRB1*13:144	-						5								14		16	17		19				
DRB1*13:157, DRB1*14:67	-						6								14			17		19				
DRB1*13:159/13:171:01/13:179	-						6								14			17	18					
DRB1*13:160/13:218	-														14			w						
DRB1*13:163/13:181/13:193, DRB1*14:02:08/14:06:01-14:06:06/14:12:01-14:12:02/14:17/14:29/14:52/14:80-14:81/14:83/14:108/14:121/14:165/14:176/14:212	-, DR14(6), DR6																	17		19				
DRB1*13:183/13:200N/13:248-13:249N/13:299	-, Null														14									
DRB1*13:191/13:217	-														14			17	18					

Alleles	Serology	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23
DRB1*13:196/13:312, DRB1*14:19/14:24/14:109/14:226	-, DR14(6)						6											17						
DRB1*13:199	-						6								14		16	w		19				
DRB1*13:223/13:234	-														w			17						
DRB1*13:228	-															15								
DRB1*13:296	-						6								w			17						
DRB1*13:302	-						6								14		16	17	18	19				
DRB1*14:13/14:85	DR14(6), -						6									15		17		19				
DRB1*14:18/14:33/14:59/14:64/14:106/14:133/14:154	DR6, -																	17	18	19				
DRB1*14:39/14:54:02/14:61/14:199	-																			18				
DRB1*14:46/14:222N	-, Null						6														19			
DRB1*14:48	-						6											w		19				
DRB1*14:51/14:134/14:200	-						6											17	18	19				
DRB1*14:54:08	-																	w	18					
DRB1*14:63	-						6								14	15		17		19				
DRB1*14:78	-														14	15		17		19				
DRB1*14:98	-						6											17		w				
DRB1*14:104/14:111	-				w													17	18					
DRB1*14:125	-																	w	w					
DRB1*14:141, DRB3*01:01:02:01-01:07/01:09-01:13/01:15-01:33/01:35-01:41/01:43-01:45/01:47-01:51/01:53-01:67/01:69-01:70/01:72-01:94/01:96-01:100, DRB3*02:01-02:05:02/02:07-02:17/02:19/02:21-02:25/02:28-02:46/02:48-02:57/02:59-02:65/02:67N-02:77/02:79-02:90/02:92-02:108/02:110/02:112-02:116/02:118-02:123/02:125N-02:130/02:132-02:142/02:144-02:159/02:161/02:163-02:178, DRB3*03:01:01:01-03:01:12/03:01:14-03:21/03:23-03:32/03:34-03:45/03:47-03:55	-, DR52, Null																					21		
DRB1*14:148	-									9										18				
DRB1*14:161	-							7										17	18					
DRB1*14:170	-															15		17		19				
DRB1*14:171	-				4													17	18					
DRB1*14:205:02	-									?								17	18					
DRB1*15:01:01:01-15:01:21/15:01:23-15:20/15:22-15:33/15:35-15:98/15:100-15:108/15:110-15:112/15:114-15:206	DR15(2), -, DR2, Null		2																					
DRB1*15:21, DRB1*16:09:01-16:10:02/16:33/16:36-16:37/16:58/16:66	-, DR16(2)		2	3																				

Alleles	Serology	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23
DRB1*15:99/15:109	-		2										12											
DRB1*15:113N	Null		w																					
DRB1*16:01:01:01-16:01:08/16:01:10-16:05:02/16:07/16:11-16:15/16:17-16:26/16:28-16:32/16:34-16:35/16:38:01-16:49/16:51-16:57/16:59Q-16:65/16:67-16:72	DR16(2), -, DR2, Null			3																				
DRB1*16:01:09	-		w																					
DRB1*16:08	-			3			6								14		16			w				
DRB1*16:16/16:27	-			3									12											
DRB3*01:08/01:46/01:52/01:71, DRB3*02:20	-						6															21		
DRB3*01:14	-				w													w						
DRB3*01:42, DRB3*02:18	-												12									21		
DRB3*02:06	-						?															21		
DRB3*02:78/02:109N/02:117/02:124/02:162, DRB3*03:01:13/03:46	-, Null																					w		
DRB4*01:01:01:01/01:01:01:03/01:02-01:03:01:01/01:03:01:03-01:03:01:12/01:03:01:14-01:03:02:02, DRB4*02:01N	DR53, -, Null																						22	
DRB4*01:03:01:02N/01:03:01:13N	Null																							23
DRB5*01:01:01:01-01:01:09/01:01:11-01:02:01/01:03-01:12/01:14-01:25/01:27N-01:40/01:42-01:47/01:49N-01:50/01:52N-01:72/01:75-01:78/01:80-01:86/01:88-01:96/01:98-01:109/01:111-01:112/01:114-01:119, DRB5*02:02:01-02:31	DR51, -, Null																					20		
DRB5*01:02:02/01:26/01:48N/01:74/01:113	-, Null																					w		

w = weak

? = nucleotide sequence information not available for the primer matching sequence (HLA-DRB1*08:04:02 is not listed) or alleles with unknown reactivities

14. Certificate of Analysis



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CTS Collaborative Transplant Study

Certificate of Analysis

HLA-DRB1* CTS-PCR-SSP Tray Kit

Product number	104
Lot number	DR43-2
Number of HLA-specific primer mixes per test	23

Mix specifications

The specificity of each primer pair has been tested against a panel of well characterized DNAs.

Result

No false positive or false negative amplifications were obtained under our test conditions of the bulk reagents.

Date of approval	30.06.2022
Approved by	H. Tran, M.D. Quality Control, Supervisor